

Exhibit D

EXHIBIT D:
ANALYSES OF BMS AND OTN SALES DATA AND MONTANA AND NEVADA
REIMBURSEMENT AND REBATE DATA

A. DATA USED

1. BMS and OTN invoice and chargeback data are in 18 files: Pre1997-Direct.txt, DirectSales_IncludingPHS.txt, Pre1997-Indirect.txt, Chargebacks_IncludingPHS.txt, OTN Blenoxane_Pre1997.txt, OTN Blenoxane.txt, OTN Cytoxan_Pre1997.txt, OTN Cytoxan.txt, OTN Paraplatin_Pre1997.txt, OTN Paraplatin.txt, OTN Taxol_Pre1997.txt, OTN Taxol.txt, OTN Vepesid_Pre1997.txt, OTN Vepesid.txt, ChargebackSupplement_Production.txt, DirectSalesSupplement_Production.txt, CoumadinSupplementalChbk.txt, and Coumadin Direct Sales_Pre 100197.txt (collectively “BMS/OTN data”).
2. BMS rebates are in 3 files: CARS_IS Data_MT_NV_1.txt, CARS_IS Data_MT_NV_2.txt, and sappmnts with filenames.xls.
3. Montana and Nevada Medicaid rebates are in MT & NV Medicaid Rebate Data 1991-2005.xls.
4. Montana Medicaid reimbursements are in drug_90_05.txt.
5. Nevada Medicaid reimbursements are in drugclaims1991.txt - drugclaims2003.txt.
6. NDC Package size data are in fdb_rndc_working.sas7bdat.
7. BMS WLPs are in PricingRevised.xls, buspar_rubex.xls, and WLP PRICING FOR MONTANA MDL.xls.
8. BMS AWP are in Data for Pricing History Charts.xls and awp_ps_transposed.sas7bdat.

B. GENERAL DATA TREATMENT

9. Some NDCs in the BMS and OTN data files were shorter than the standard 11-digit length. Using the NDC descriptions provided with the data and

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<http://www.fda.gov/cder/ndc/database/> as an independent source for NDCs, a crosswalk was created to standardize the NDCs in the BMS/OTN data. Using the crosswalk, the shorter NDCs were corrected by inserting the missing leading zeroes, as did Dr. Hartman.

10. The quantity is set to zero in Sharp transactions with reason codes '05' or '53', as does Dr. Hartman.
11. The quantity is set to zero in Sharp and OTN transactions where the "ext_amt" is equal to zero or empty.
12. In the BMS/OTN data files, the invoice date fields are standardized and customer categories are assigned based on the customer category code (CCC) and the customer billing category fields.
13. The BMS Invoice data and BMS Chargeback data are each then divided into two customer groups, Federal Government (including classes of trade otherwise eligible for special pricing terms, such as PHS hospitals), and Non-Federal Government (all categories not classified as Federal Government), based on the customer category. Transactions are classified as Federal Government if the CCC is '31', '32', '33', '34', '35', '39', '41', '42', '43', '45', or '95' and the customer billing category is '50' or '55'. In addition, transactions with a CCC of '52' or '952' and a customer billing category of '55' are classified as Federal Government.¹ All the records in the OTN data are classified as Non-Federal Government.
14. BMS Invoice data and BMS Chargeback data are also divided into retail and non-retail customers. Transactions are classified as retail when the CCC is '82', '83', '84', '85', '86', and '87'.

¹ There may be Federal Government transactions left in the Non-Federal Government data that cannot be easily identified. Consequently, the results in Exhibits E, F and G are conservative.

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C. SUMMARY OF REVENUE BY PRODUCT IN EXHIBIT E

15. In the BMS and OTN data files, the sales/chargebacks and quantity fields are aggregated by customer group (Federal Government or Non-Federal Government), NDC, and month.
- Dollar sales and quantity in BMS Invoice data are aggregated by customer group, NDC, and month to BMS Invoice Revenue and BMS Invoice Quantity.
 - Chargeback Dollar amounts and chargeback quantity in BMS Chargeback data are aggregated by customer group, NDC, and month to Chargeback Dollars and Chargeback Quantity.
 - OTN Dollar sales and quantity in OTN data are aggregated by customer group, NDC, and month to OTN Revenue and OTN Quantity.
16. Revenue at WLP is calculated by multiplying the total Non-Federal Quantity by the WLP. Prior to May 2001, the total Non-Federal Quantity is BMS Non-Federal Invoice Quantity plus, where applicable,² OTN Quantity minus the Chargeback Federal Quantity; after May 2001, it is just BMS Non-Federal Invoice Quantity minus the Chargeback Federal Quantity because starting in May 2001, OTN sales are recorded in both the BMS and OTN invoice data.
17. Net revenue is calculated by year and product by adding BMS Non-Federal Gross Revenue to OTN Revenue and then subtracting Non-Federal Chargeback Dollars and Rebates.³

² All references to OTN data are applicable only to the oncology products at issue in these cases.

³ There is a difference in the timing of sales and their associated chargebacks that may cause net revenues to be overstated or understated. Taxol in 2002 appears to be a prime example of an understatement of net revenues due to chargebacks from 2001 flowing into a year, 2002, in which sales declined rapidly.

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D. BMS/OTN PRICE DISPERSION IN EXHIBIT F

18. To calculate the BMS/OTN Price Dispersion in Exhibit F, BMS Non-Federal transactions are separated into four categories: 1) BMS Direct Transactions to Non-Wholesalers, 2) OTN Transactions, 3) BMS Indirect Transactions Generating Chargebacks, and 4) BMS Direct Transactions to Wholesalers Not Generating Chargebacks. For each category, the price associated with each transaction is computed relative to the BMS WLP. After the price relative to WLP is computed for each transaction, the net revenues are aggregated according to the price intervals as a percentage of WLP shown in Exhibit F and the distribution of net revenue for each product for each year is computed accordingly. Net revenue in category 3) is computed as the revenue per the invoice price less the chargeback. In the other three categories, net revenue is the revenue per the invoice price. Due to the transaction-level nature of this analysis, rebates are not considered but are immaterial.⁴

i. Four Transaction Categories

a) BMS Direct Transactions to Non-Wholesalers

19. For each direct transaction to a non-wholesaler in the BMS invoice data, the invoice price is compared to the WLP and the difference as a percent is computed.

b) OTN Transactions

20. For each transaction in the OTN invoice data, the invoice price is compared to the WLP and the difference as a percent is computed. Any OTN Taxol and Paraplatin rebates are not taken into account.⁵

⁴ In total, rebates account for less than 1.27 percent of net revenue from 1993 through 2002 for the BMS products at issue.

⁵ In total, OTN Taxol and Paraplatin rebates account for less than 0.3 percent of OTN Taxol and Paraplatin net sales from 1993 through 2002 and 1.2 percent of OTN Taxol and Paraplatin net sales from 2001 through 2002. The Paraplatin and Taxol rebates start on 12/29/00 and on 8/31/01, respectively. (OTN Rebate Paraplatin.txt, OTN Rebate Taxol.txt, and Exhibit E.)

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c) BMS Indirect Transactions Generating Chargebacks

21. For each transaction where the product is purchased from a wholesaler and a chargeback is generated, the price after netting out the chargeback is compared to the WLP and the difference as a percent is computed.

d) BMS Direct Transactions to Wholesalers Not Generating Chargebacks

22. [This is still clear as mud. Could we briefly comment on what these transactions are and why we jump through these hoops?] The set of transactions remaining after the first three categories includes BMS direct transactions to wholesalers that did not generate chargebacks. These transactions are examined as follows.
- a. Annual unit sales to wholesalers (using the CCC field) in the BMS invoice data and annual unit sales in the chargeback data are computed by NDC.
 - b. Direct sales to wholesalers are adjusted to remove the BMS transactions to wholesalers generating chargebacks (i.e. indirect transactions) and, beginning in May 2001, OTN transactions by applying an adjustment ratio to each wholesaler transaction.⁶ The adjustment ratios are computed by year and NDC as the ratio of indirect transactions not associated with chargebacks nor from OTN to all indirect transactions. Before May 2001, the numerator of the adjustment ratio is the chargeback quantity. Beginning in May 2001, the numerator of the adjustment ratio is computed as the sum of the OTN quantity and the chargeback quantity. This numerator is divided by the wholesaler invoice quantity to yield the percent of indirect units not generating chargebacks nor related to OTN sales. These adjustment ratios are applied to each wholesaler transaction to effectively remove the transactions with a chargeback or that go through OTN. The effect of applying these adjustments is to net the sales

⁶ Starting in May 2001, OTN sales are recorded in both the BMS and OTN invoice data.

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to wholesalers generating chargebacks from the total sales to wholesalers.⁷

For each adjusted transaction, the invoice price is compared to the WLP.

The effect of this method is that the price distribution of this remainder set of transactions reflects the distribution of all BMS indirect transactions.⁸

E. SUMMARY OF BMS/OTN REVENUE AND REBATES BY PRODUCT IN EXHIBIT G

23. The methodology for Exhibit G is the same as for Exhibit E. In addition to Revenue at WLP and Net Revenue, Exhibit G also accounts for Rebates and includes a corresponding Net Revenue with Rebates.
24. Rebates are calculated from the ‘sapchecks’ worksheet of the file sappmnts with filenames.xls and CARS_IS Data_MT_NV_1.txt and CARS_IS Data_MT_NV_2.txt.
- a. Rebates to “VHA” were excluded from the ‘sapchecks’ worksheet. The “reason” column in these data is used to identify the price concession type, period, and product(s). As an example for the period, a rebate with “3Q Multisource Admin Fee Dec 99-Feb 00” as the reason is assigned to December 1999, January 2000, and February 2000. When the period is not evident from the reason, the rebates are assigned using the period length in the reason, if provided, and the check issue date.
 - b. For rebates associated with one product, rebates are assigned to quarters based on the period. If the period spanned more than one quarter, the rebate amount is divided among the quarters based on the number of days

⁷ As a result of differences in the timing of sales and their associated chargebacks, the sales volume to wholesalers not generating chargebacks may be overstated or understated. For example, suppose the sales volume drops sharply from Year 1 to Year 2. In this situation, the Year 2 chargebacks are likely to overstate the chargebacks truly associated with Year 2 sales. Consequently, after deducting the Year 2 chargebacks from the Year 2 sales, the Year 2 sales to wholesalers not generating chargebacks are likely to be understated.

⁸ When the calculated adjustment ratio for a specific NDC in a specific year is negative, the adjustment ratio is set to zero. This step may cause a slight divergence between the price distribution imputed for this set of transactions versus the price distribution of all BMS indirect transactions.

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in each quarter. If the reason included months, this is done on a monthly level. For example, a rebate for Feb-Apr 2000 is divided between 2000Q1 and 2000Q2 based on the number of days in each quarter: $(29+31) \div 90 = 66.67\%$ of the rebate is allocated to Q1, while $30 \div 90 = 33.33\%$ of the rebate is allocated to Q2.

- c. For rebates associated with more than one product, such as Taxol/Paraplatin, rebate amounts are apportioned between products based on the quarterly net revenue by product.
- d. Rebates are aggregated to the product and quarter. These amounts are then apportioned among NDCs according to quarterly net revenue.
- e. Rebates from CARS_IS Data_MT_NV_1.txt and CARS_IS Data_MT_NV_2.txt are classified into customer categories by customer names. Rebates to Federal Government categories are dropped. Rebates are then aggregated by NDC and quarter.
- f. Rebates are aggregated to the product and quarter.

F. CARS IS REBATES BY CUSTOMER SEGMENT IN EXHIBIT H

- 25. The CARS_IS Data_MT_NV_1.txt and CARS_IS Data_MT_NV_2.txt are assigned customer segments based on the variable "bunit_name." Customers are designated as Alternative Care, Employer, Gov't Agencies (Non-Federal), HMO/PBM, Hospitals, Lab, Mail Order, PHS, Physicians/Clinics, Retail, Unclassifiable, Union, or Wholesaler/Distributor through the use of public sources.
- 26. NDCs that are not part of this case are dropped.
- 27. The rebates are aggregated by product, customer segment, and year.

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G. MONTANA (NEVADA) MEDICAID REBATES BY PRODUCT AND YEAR IN EXHIBIT I-1 (I-2)

- 28. Montana and Nevada Medicaid rebate data is limited to NDCs at issue.
- 29. Rebates are aggregated by product and year.

H. MONTANA (NEVADA) MEDICAID REIMBURSEMENT ANALYSIS IN EXHIBIT J-1 (J-2)

- 30. Total Units, Total Scripts, Capped State Reimbursement, Pharmacy Acquisition Cost, Pharmacy Profit, State Payment at Statute Amount, State Payment at AWP, and State Payment at WLP are calculated at the claim level and from the Montana and Nevada Medicaid Reimbursement data.
- 31. The Medicaid Reimbursement data is limited to the NDCs at issue.
- 32. Total Units is simply drug claim quantity aggregated by NDC, quarter, and year.
- 33. Total Scripts is a count of the number of claims. For Nevada, claims were excluded when the minimum of “sami_amt” and “bill_amt” is less than the “dispensing fee.”
- 34. Capped State Reimbursement is the lesser of State Payment at Statute Amount or actual State Reimbursement.
 - a. State Payment at Statute Amount is calculated by multiplying AWP by the ratio of drug claim quantity and package size; up until July 2002, this variable is multiplied by 0.9; starting in July 2002, it is multiplied by 0.85.
 - b. State Reimbursement is calculated by subtracting the dispensing fee from the claim reimbursement amount.
- 35. Pharmacy Acquisition Cost is calculated by multiplying WLP by the ratio of drug claim quantity and package size.

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36. Pharmacy Profit is created by subtracting Pharmacy Acquisition Cost from Capped State Reimbursement.
37. The Montana and Nevada variables are aggregated by product and year.
38. State Net Payment is calculated by merging the Montana (Nevada) Medicaid Reimbursement data and the corresponding rebate data.
 - a. The Medicaid rebates are limited to the NDCs at issue.
 - b. The rebate data is aggregated by product and year and merged by product and year to the reimbursement data.
 - c. State Net Payment is computed by subtracting rebate from Capped State Reimbursement.

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I. NDCs INCLUDED IN ANALYSIS

<u>NDC</u>	<u>Product</u>	<u>NDC</u>	<u>Product</u>	<u>NDC</u>	<u>Product</u>
00015050301	Cytosan Tablets	00056017270	Coumadin	00087277131	Avapro
00015050302	Cytosan Tablets	00056017275	Coumadin	00087277132	Avapro
00015050401	Cytosan Tablets	00056017290	Coumadin	00087277215	Avapro
00015054641	Cytosan	00056017370	Coumadin	00087277231	Avapro
00015054741	Cytosan	00056017375	Coumadin	00087277232	Avapro
00015054841	Cytosan	00056017470	Coumadin	00087277235	Avapro
00015054941	Cytosan	00056017475	Coumadin	00087277315	Avapro
00015111750	Tequin	00056017670	Coumadin	00087277331	Avapro
00015111780	Tequin	00056017675	Coumadin	00087277332	Avapro
00015117760	Tequin	00056017690	Coumadin	00087606005	Glucophage
00015117780	Tequin	00056018870	Coumadin	00087606010	Glucophage
00015301020	Blenoxane	00056018875	Coumadin	00087606313	Glucophage XR
00015306120	VePesid	00056018890	Coumadin	00087607005	Glucophage
00015306220	VePesid	00056018970	Coumadin	00087607111	Glucophage
00015306301	Blenoxane	00056018975	Coumadin	00087607211	Glucovance
00015308420	VePesid	00056018990	Coumadin	00087607311	Glucovance
00015309145	VePesid Capsules	00087003147	Serzone	00087607411	Glucovance
00015309520	VePesid	00087003231	Serzone	00087667117	Videx EC
00015321329	Paraplatin	00087003331	Serzone	00087667217	Videx EC
00015321330	Paraplatin	00087003931	Serzone	00087667317	Videx EC
00015321429	Paraplatin	00087004131	Serzone	00087667417	Videx EC
00015321430	Paraplatin	00087015846	Monopril	00087771840	Cefzil Suspension
00015321529	Paraplatin	00087015885	Monopril	00087771862	Cefzil Suspension
00015321530	Paraplatin	00087060942	Monopril	00087771864	Cefzil Suspension
00015347530	Taxol	00087060945	Monopril	00087771940	Cefzil Suspension
00015347630	Taxol	00087060985	Monopril	00087771962	Cefzil Suspension
00015347911	Taxol	00087081841	Buspar	00087771964	Cefzil Suspension
00056016870	Coumadin	00087081844	Buspar	00087772060	Cefzil Tablets
00056016875	Coumadin	00087081941	Buspar	00087772150	Cefzil Tablets
00056016890	Coumadin	00087081944	Buspar	00087772160	Cefzil Tablets
00056016970	Coumadin	00087082232	Buspar	63653117101	Plavix
00056016975	Coumadin	00087082233	Buspar	63653117103	Plavix
00056016990	Coumadin	00087082481	Buspar	63653117105	Plavix
00056017070	Coumadin	00087120213	Monopril	63653117106	Plavix
00056017075	Coumadin	00087149201	Monopril HCT		
00056017090	Coumadin	00087149301	Monopril HCT		